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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LU, FRANK WEI MIN

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/642,749

Applicant(s)

SU ET AL.

Examiner

Frank W Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/16/2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-14 and 23 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10 and 23 is/are rejected.
- 7) ☒ Claim(s) 11-13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10. 6) ☐ Other:

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DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on May 16, 2003 has been entered. The claims pending in this application are claims 10-14 and 23 with claim 14 withdrawn from consideration as the result of the restriction requirement. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the amendment filed on May 16, 2003.

Information Disclosure Statement

2. "Applicants request that the Examiner consider the Information Disclosure Statement and cites documents filed August 18, 200 and return with the next communication a copy of the Form PTO-1449 as considered and initialed by the examiner." has been considered. However, the examiner does not understand why applicant asks the examiner to return Form PTO-1449 filed on August 18, 2000 again since this Form PTO-1449 was initialed and mailed to applicant on previous office action. In order to response applicant's request, the examiner has attached this Form PTO-1449 to this office action.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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4. Claims 10 and 23 are rejected under 35 U.S.C. 102(a) as being anticipated by Shah *et al.*, (Proc. Natl. Acad. Sci. USA, 94, 3565-3570, April 1997).

Shah *et al.*, teach several mutants of protein tyrosine kinase v-Src which has mutations in its ATP binding site. One of protein tyrosine kinase v-Src mutant, GST-XD4 (V323A, I338A) bound to ATP with K_m $150 \pm 20 \mu M$ (130-170 μM). This dissociation constant (K_m) was 10-fold lower than dissociation constant (K_m) of the binding of GST-XD4 (naturally-occurring protein tyrosine kinase v-Src) to ATP [$12 \pm 3 \mu M$ (9-15 μM)] (see abstract in page 3565, Figure 3c and Table 1). Here ATP is considered as a compound as recited in claims 10 and 23 since ATP binds to an ATP binding site of different tyrosine protein kinases. Since K_m for GST-XD4 binding to ATP is 9-15 μM while K_m for GST-XD4(V323A, I338A) binding to ATP is 130-170 μM , the dissociation constant of GST-XD4 (V323A, I338A) (ie., mutant protein tyrosine kinase v-Src) binding to ATP (ie., compound) is 10-fold lower than dissociation constant of GST-XD4 ((ie., naturally occurring protein tyrosine kinase v-Src) binding to ATP (ie., compound) as recited in claims 10 and 23.

Therefore, Shah *et al.*, teach all limitations recited in claims 10 and 23.

Response to Arguments

In pages 6, second paragraph of applicant's remarks, applicant argues that "GST-XD4 does not have at least one amino acid substitution in its ATP binding site compared to the naturally occurring protein kinase, as required by claim 10. Further, although Shah demonstrates that the wild-type kinase binds to ATP with a K_m of $12 \pm 3 \mu M$, the mutant kinase described by Shah binds to neither ATP nor N^6 -(cyclopentyl) ATP with a K_m of less than 10 μM . See

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Table 1 on page 3569 of Shah.”.

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. The examiner agrees with applicant that “GST-XD4 does not have at least one amino acid substitution in its ATP binding site” and “although Shah demonstrates that the wild-type kinase binds to ATP with a K_m of $12 \pm 3 \mu M$, the mutant kinase described by Shah binds to neither ATP nor N^6 -(cyclopentyl) ATP with a K_m of less than $10 \mu M$.”. However, since K_m for GST-XD4 binding to ATP is $9-15 \mu M$ while K_m for GST-XD4(V323A, I338A) binding to ATP is $130-170 \mu M$, the dissociation constant of GST-XD4 (V323A, I338A) (ie., mutant protein tyrosine kinase v-Src) binding to ATP (ie., compound) is 10-fold lower than dissociation constant of GST-XD4 (ie., naturally occurring protein tyrosine kinase v-Src) binding to ATP (ie., compound) as recited in claims 10 and 23.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

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1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5. Claims 11-13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

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Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
July 10, 2003



**ETHAN WHISENANT
PRIMARY EXAMINER**